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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,594	07/01/2003	Sheng-Ping L. Hwang	ACAD/0002	3435

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,594	HWANG ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-5 and 20-22, drawn to a nucleic acid encoding a BMP4 gene and a cell comprising said DNA molecule, classified in class 530, subclass 23.1; class 435, subclass 325.

II. Claims 6-19, drawn to a transgenic embryo or fish comprising a nucleic acid encoding a BMP4 gene, classified in class 800, subclass 20.

III. Claims 23,26,27,30,31 and 35, drawn to an in vitro method of screening for compounds that regulate BMP-4 expression by administering a compound to isolated cells comprising a BMP-4 expression vector, classified in class 435, subclass 4.

IV. Claims 23-26 and 28-36, drawn to an in vivo method of screening for compounds that regulate BMP-4 expression by administering a compound to cells in an embryo comprising a BMP-4 expression vector, classified in class 800, subclass 3.

V. Claims 37 and 39, drawn to an in vitro method of screening for effectors that regulate BMP-4 expression comprising introducing foreign cDNA into cells in vitro that contain a recombinant expression vector encoding a BMP4 regulatory region, classified in class 435, subclass 6.

VI. Claims 37-39, drawn to drawn to an in vivo method of screening for effectors that regulate BMP-4 expression comprising introducing foreign cDNA into cells of an

embryo that contain a recombinant expression vector encoding a BMP4 regulatory region, classified in class 514, subclass 44; class 800, subclass 3.

VII. Claims 40,41 and 44, drawn to a method of identifying an expression pattern of a BMP-4 sequence using a cell in vitro comprising a BMP-4 expression sequence operatively linked to a reporter gene, classified in class 435, subclass 6.

VIII. Claims 40-43 and 45, drawn to a method of identifying an expression pattern of a BMP-4 sequence using an embryo or fish in vivo comprising a BMP-4 expression sequence operatively linked to a reporter gene, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because Invention I is drawn to a nucleic acid encoding BMP4 or its regulatory region whereas Invention II is drawn to a transgenic embryo or fish, in vivo, that comprises the nucleic acid. The inventions have different structure and have different modes of use. The nucleic acid can be used as a probe or to make protein in vitro while the embryo or fish can be used to screen compounds for in vivo BMP4 modulators. Furthermore, the nucleic acid and the embryos and fish are classified differently. It would require undue burden to search Inventions I and II together.

Invention I and each of Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Invention I can be used to make

protein. Furthermore, the method of Inventions III and V can be carried out in vivo rather than in the isolated cells of Invention I.

Invention I and each of Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used as a probe or in cells in vitro and the cells can be used to make protein. Furthermore, the method of Inventions IV and VI can be carried out in vitro rather than in embryos or fish.

Invention I and each of Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used as a probe or in cells in vitro or in cells of an embryo or fish. The cells can be used to make protein.

Invention II and each of Inventions III and V are patentably distinct because Invention II is drawn to a transgenic embryo or fish while Inventions III and V are drawn to in vitro methods of screening. The embryo and fish do not require the method and vice versa. The inventions are classified differently. It would require undue burden to search together Invention II with either of Inventions III and V.

Invention II and each of Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the embryo or fish of Invention II can be used in either of the methods of Inventions IV and VI.

Invention II and Invention VII are patentably distinct because Invention II is drawn to a transgenic embryo or fish while Invention is drawn to a method of using cells in vitro. The methods are not necessary for the embryo or fish and vice versa. The embryo and fish are classified differently from the in vitro methods. It would require undue burden to search Invention II together with Invention VII.

Invention II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the embryo of Invention II can be used in the methods of Inventions IV and VI.

Invention III and each of Inventions IV and VI are patentably distinct. The methods use different reagents and have different technical considerations. Invention III is drawn to in vitro methods of screening whereas Inventions IV and VI are drawn to in vivo methods of screening. The methods are not necessary one for the other. The methods are classified differently. It would require undue burden to search Invention III with either of Inventions IV or VI.

Inventions III and V are patentably distinct. The methods of Invention IIII are drawn to s in vitro methods of screening for compounds that regulate BMP-4 expression. The methods of

Invention V are drawn to a method of screening nucleic acids by introducing DNA into cells of an embryo. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Inventions III and V together.

Inventions III and VII are patentably distinct. The methods of Invention III are drawn to screening compounds for BMP modulatory activity. The methods of Invention VII are drawn to a method of screening DNA fragments for promoter activity. The reagents and process steps used to carry pout the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Inventions III and VII together.

Inventions III and VIII are patentably distinct. The methods of Invention III are drawn to screening compounds for BMP modulatory activity in vitro. The methods of Invention VIII are drawn to a method of screening DNA fragments for promoter activity in vivo. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Inventions III and VIII together.

Invention IV and each of Inventions V and VII are patentably distinct. The methods use different reagents and have different technical considerations. Invention IV is drawn to in vivo methods of screening compounds whereas Inventions V and VII are drawn to in vitro methods of screening. The methods are not necessary one for the other. The methods are classified differently. It would require undue burden to search Invention IV with either of Inventions V or VII.

Inventions IV and VI are patentably distinct. The methods of Invention IV are drawn to screening compounds for BMP modulatory activity. The methods of Invention VI are drawn to a method of screening nucleic acids by introducing DNA into cells of an embryo. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Inventions IV and VI together.

Inventions IV and VIII are patentably distinct. The methods of Invention IV are drawn to screening compounds for BMP modulatory activity in. The methods of Invention VIII are drawn to a method of screening DNA fragments for promoter activity. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Inventions IV and VIII together.

Inventions V and VI are patentably distinct. The methods use different reagents and have different technical considerations. Invention V is drawn to in vitro methods of screening whereas Invention VI is drawn to in vivo methods of screening. The methods are not necessary one for the other. The methods are classified differently. It would require undue burden to search Inventions IV and VI together.

Invention V and each of Inventions VII and VIII are patentably distinct. The methods of Invention V are drawn to screening compounds for BMP modulatory activity in vitro. The methods of Inventions VII and VIII are drawn to a method of screening DNA fragments for promoter activity in vitro or in vivo. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Invention V with either of VII or VIII.

Invention VI and each of Inventions VII and VIII are patentably distinct. The methods of Invention VI are drawn to screening compounds for BMP modulatory activity in vivo. The methods of Inventions VII and VIII are drawn to a method of screening DNA fragments for promoter activity in vitro or in vivo. The reagents and process steps used to carry out the inventions are distinct and different. The methods are not required one for the other. It would require undue burden to search Invention VI with either of VII or VIII.

Inventions VII and VIII are patentably distinct. The methods use different reagents and have different technical considerations. Invention VII is drawn to in vitro methods of screening DNA for promoter activity whereas Invention VIII is drawn to in vivo methods of screening. The methods are not necessary one for the other. The methods are classified differently. It would require undue burden to search Inventions VII and VIII together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632